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DOCKET NO.: 197759US0CONT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
AKIHIRO KISHISHITA, ET AL.	: EXAMINER: ZUCKER, P. A.
SERIAL NO: 09/708,006	:
FILED: NOVEMBER 8, 2000	: GROUP ART UNIT: 1621

FOR: NOVEL ASPARTAME DERIVATIVE CRYSTAL AND PROCESS FOR PRODUCING THE SAME:

DECLARATION OF PROFESSOR JERRY ATWOOD

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313

SIR:

Now comes Professor Jerry Atwood, who declares and states:

1. I reside at 5704 Short Line Dr., Columbia, Missouri 65203. I hold a B.S. degree in Chemistry and Mathematics from Southwest Missouri State University (1964) and a Ph.D. in Chemistry from the University of Illinois (1968).

2. Since 1994, I have been employed as Professor and Chairman of the Department of Chemistry at the University of Missouri-Columbia. From 1968 to 1994, I was employed by the University of Alabama, where I successively held the titles of Assistant Professor, Associate Professor, Professor, and University Research Professor. In 1999, I became Curators' Professor at the University of Missouri-Columbia.

3. From 1985 to 1998, I was Editor of the *Journal of Chemical Crystallography*. In 1999 I was named Consulting Editor for the *Journal of Chemical Crystallography*. I have edited the *Journal of Supramolecular Chemistry* since 2000, and I have been Associate Editor

of *Chemical Communications* since 1996. From 1992 until 2000, I was editor of *Supramolecular Chemistry*. From 1985 to 1993, I was Regional Editor for the *Journal of Coordination Chemistry*. I am co-Editor of the *Inclusion Compounds* book series (five volumes), *Comprehensive Supramolecular Chemistry* (ten volumes) and the *Encyclopedia of Supramolecular Chemistry* (two volumes). I currently serve on the Editorial Boards of *Crystal Growth & Design, Crystal Engineering*, the *New Journal of Chemistry, Supramolecular Chemistry*, and the *Journal of Coordination Chemistry*. I have published more than 500 articles in refereed journals. I have authored ten patents. I am an expert in the fields of crystal growth, crystal engineering, and polymer chemistry. A copy of my curriculum vitae is attached hereto as Appendix A. I have consulted widely for industry, particularly in the fields of pharmaceutical chemistry and polymer chemistry.

4. I am being compensated at my regular consulting rate for my time spent in preparing this opinion.

5. At the request of Ajinomoto Co., Inc., the assignee of the above-identified application by virtue of assignment recorded at reel/frame: 011466/0725 (recorded January 26, 2001), I have reviewed:

a. the file history of U.S. Patent Application Serial No. 09/708,006 ("the Application") including the specification and all pending claims, filed on November 8, 2000, entitled "Novel Aspartame Derivative Crystal and Process For Producing The Same";

b. U.S. Patent No. 5,480,668, issued to Nofre et al. (the Nofre '668 Patent);

c. U.S. Patent No. 4,810,818, issued to Wakamatsu et al. (the Wakamatsu '818 Patent);

d. U.S. Patent No. 4,579,747, issued to Sugiyama et al. (the Sugiyama '747 Patent).

I have also reviewed the Office Action issued in the Application and dated August 26, 2003 ("the Office Action") and provide the following comments on the scientific basis therefor.

6. In paragraph 5 of the Office Action, beginning with line 6, the examiner states:

> "Wakamatsu teaches (Column 3, lines 11-43) a method of producing a more easily soluble crystalline form of aspartame which comprises granulation and drying the aspartame to a water content of 2.6% by weight. Wakamatsu further teaches (Column 2, lines 17-18) a range of granule size of 0.1 to 10 mm which embraces the instant range of 100-1,400 μm (which corresponds to 0.1-1.4 mm)."

7. The next paragraph states:

> "The difference between the instant invention and that taught by Wakamatsu is that Wakamatsu does not suggest the use of N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine 1-methyl ester (Neotame) in this process to create a more soluble form of neotame."

8. The next paragraph states:

> "Nofre, however, teaches (Column 4, line 65-Column 5, line 10) Neotame and its synthesis (Column 6, lines 27-54) from Aspartame to which it is a close analog. Nofre further teaches (Column 1, lines 10-19) the use of Neotame as a sweetening agent in food and drinks as well as its use (Column 6, lines 16-26) in conjunction with other sweeteners such as sucrose and saccharin. Nofre further teaches (Column 6, lines 8-16) its use in conjunction with carriers or bullking agents such as polydextrose, starch, maltodextrins, and cellulose. Nofre teaches (Column 4, lines 29-37) the use of Neotame for all uses of the known sweetener aspartame."

9. The examiner then concludes:

> "Thus the instantly claimed invention would have been obvious to one of ordinary skill in the art. The motivation for performing this invention would have been to provide the same improved solubility for Neotame that the process of Wakamatsu provided for its close analog Aspartame, a commercially important sweetener. Because of the very close structural similarity of Neotame and Aspartame and the large overlap in their chemical and physiological behavior and intended uses the expectation for success would have been reasonable."

10. In the paragraphs that follow, I describe the state of the art with regard to the relationship of compounds with specific atoms and bonds to the crystallization and physical properties of such compounds. I then relate the teachings of the Nofre '668 Patent in light of the teachings of the Wakamatsu '818 Patent to the teachings of the Application. In summary,

my opinion is that the Application contains new teachings not found in a combination of the Nofre '668 Patent and the Wakamatsu '818 Patent.

11. Many organic compounds crystallize in more than one form. That is to say, one given organic compound may crystallize in two or more different forms. These forms are not different in the way in which the atoms of the molecule are connected, but rather in the manner in which the molecules relate to each other in the crystalline state. This behavior is referred to as polymorphism. In 1965, McCrone defined a polymorph as "a solid crystalline phase of a given compound resulting from the possibility of at least two different arrangements of the molecules of that compound in the solid state" (W. C. McCrone in *Physics and Chemistry of the Organic Solid State*, Vol. 2, (Eds.: D. Fox, M. M. Labes, and A Weissberger), pp. 725-67, Wiley Interscience, New York, 1965).

12. Pseudopolymorphs are solvates or hydrates of a given crystalline compound. Polymorphs and pseudopolymorphs may have very different physical properties such as melting point, dissolution rate, solubility, particle size, and hygroscopicity. One polymorph may be much more useful for a given purpose than is another polymorph, even though, chemically, the molecules are the same.

13. Polymorphs were first discovered by chance. Indeed, even with the substantial effort now being brought to bear to the polymorphism issue, there is no way to predict the existence of polymorphism or pseudopolymorphism for a given compound, regardless of the information available about the manner in which the atoms are bonded together in the molecule. The American Chemical Society held a so-called "ProSpectives" course in polymorphism in February 2003, and a second such course was in February 2004. The advertisement for this 2004 course is given in Exhibit B.

14. While it is not possible to predict polymorphism, once polymorphs have been discovered, it is necessary to describe the methods and conditions of crystallization which will afford reproducibility. In my opinion, it is not sufficient to simply state that a compound

is crystallized from a given solvent. Polymorphs may be obtained even from the same solvent under different crystallization conditions.

15. Some chemical compounds do not exhibit polymorphism. In his book entitled *Polymorphism in Molecular Crystals*, Bernstein notes: "Some very common materials, such as sucrose and naphthalene, which certainly have been crystallized innumerable time, have not been reported to be polymorphic." (J. Bernstein, *Polymorphism in Molecular Crystals*, Clarendon Press, Oxford, 2002, p. 9)

16. Berstein continues: "The *possibility* of polymorphism may exist for any particular compound, but the conditions required to prepare as yet unknown polymorphs are by no means obvious. There are as yet no comprehensive systematic methods for feasibly determining those conditions. Moreover, we are almost totally ignorant about the properties to be expected from any new polymorphs that might be obtained."

17. Aspartame, aspartame hydrates, and aspartame derivatives are known to exhibit polymorphism (Leung et al., *Journal of Pharmaceutical Sciences*, Vol. 87, pp. 501-507, 1998). Five crystal modifications of Aspartame are known in the crystallization from an aqueous solution. Ajinomoto Co., as the result of "intensive investigations to improve the workability [of the crystallization] step in the production" found that cooling aqueous solutions of aspartame without stirring afforded "bundle-like" crystalline aggregates. These bundles had improved handling characteristics, and a European patent was granted for this process in 1985.

18. In the United States, patents related to polymorphs and pseudopolymorphs of important drugs are common. Indeed, it is a rare drug that does not now have polymorphs and pseudopolymorphs covered by patents. These patents may cover a given polymorph and/or methods of making a given polymorph.

19. The Application teaches the crystallization of the Aspartame derivative N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester (Neotame). A new form of the compound is disclosed and a detailed description of the conditions of crystallization is given. The resulting crystals are defined in terms of their X-ray powder diffraction (XRPD) pattern and are referred to as "C-type" crystals. Upon reading the Application, one of ordinary skill in the art would understand how to crystallize N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester, and would further know that the desired C-type crystalline compound had been prepared by performing a standard XRPD study.

20. The previously reported A-type crystals of Neotame contain water of crystallization, and the water content of the A-type crystals is generally 3-6% (inclusive of the water of crystallization). The water content of the C-type crystals is less than 3%. Thus, the C-type crystals and the A-type crystals are pseudopolymorphic forms of Neotame.

21. The C-type crystals and the A-type crystals of Neotame differ with regard to the XRPD pattern, as is disclosed in the Application. Importantly, the C-type crystals show improved solubility in water over that of the A-type crystals.

22. The Nofre '668 Patent teaches the synthesis of N-[N-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine methyl ester in column 7, lines 39-51. However, there is no detailed teaching of crystal form. In the '668 Patent, col. 7, l. 47-51, one finds:

> "The gummy precipitate formed is filtered off, dried under vacuum and recrystallized from an ethanol/water mixture (1/1) or from acetonitrile to give 9 g (yield 62%) of N-[N-(3,3-dimethylbutyl]-L-α-aspartyl]-L-phenylalanine 1-methyl ester."

23. In Example 1 of the Application, the conversion of A-type crystals to C-type crystals by drying is taught. Further, in Figure 2 of the Application the XRPD pattern of the C-type crystals of the compound is presented. This would allow one of ordinary skill in the art to compare his/her XRPD pattern and understand that he/she is practicing the art of the Application.

24. In order to test the limited teachings of the Nofre '668 Patent with regard to crystal form, Ajinomoto Company, Inc., offered testing in the declaration by Nagashima on September 21, 2001.

25. In Experimental Example 1 (page 2 of the Nagashima declaration), the test of the crystal form resulting from the recovery of N-[N-(3,3-dimethylbutyl]-L-α-aspartyl]-L-phenylalanine methyl ester from methanol solution is presented. After concentration and drying, the XRPD pattern shows that amorphous material was obtained from the methanol treatment.

26. The amorphous Neotame resulting from Experimental Example 1 was found to contain 1.4% water by weight after the drying. This means that under the conditions of methanol solution treatment and drying, C-type crystals do not result.

27. In Experimental Example 2 (page 2 of the Nagahsima declaration), the Neotame solution was treated with 1 mol/L of NaCl solution to simulate the conditions described in the Nofre '668 Patent, column 7, lines 45-47. The solid was dried to a water content of 4.2% by weight. The XRPD patterns of the wet and dried Neotame were those of A-type crystals.

28. In Experimental Example 4 (page 3 of the Nagashima declaration), Neotame was crystallized from ethanol/water, as mentioned in the Nofre '668 Patent, column 7, line 49. The solid was dried to a water content of 4.3%. The XRPD patterns of the wet and dried Neotame were those of A-type crystals.

29. In Experimental Example 3 (page 3 of the Nagashima declaration), Neotame was crystallized from acetonitrile, as mentioned in the Nofre '668 Patent, column 7, line 49. The solid was dried to a water content of 4.3%. The XRPD patterns of the wet and dried Neotame were those of A-type crystals.

30. In my opinion, the experimental work performed by Nagashima was an appropriate test of the crystallization teachings of the Nofre '668 Patent. The work was carefully done, and the quantities of reagents and the conditions were appropriate.

31. The Wakamatsu '818 Patent teaches a method of drying Aspartame so as to prevent crystal form conversion. The Aspartame is carefully dried so that Type I crystals are not converted to the less soluble Type II crystals.

32. In my opinion, the existence of two types of crystals of Aspartame does not mean that two types of crystals will exist for Neotame. The functionality of Aspartame and Neotame is similar in that they both possess the L-aspartyl-L-phenylalanine methyl ester core structure. However, the presence of the bulky dimethylbutyl group on Neotame means that the crystallization behavior of Neotame will in all likelihood be different from that of Aspartame. This means that prediction of Neotame crystallization behavior based on that of Aspartame is not backed up by sound science. The existence of polymorphs or pseudopolymorphs of Neotame must be determined by experimentation, not by analogy to Aspartame.

33. In summary, in my opinion the Application contains new teachings not found in a combination of the Nofre '668 Patent and the Wakamatsu '818 Patent. A combination of the Nofre '668 Patent and the Wakamatsu '818 Patent does not afford a reasonable prediction that C-type crystals of Neotame even exist. The Application is based on sound experimental science. The existence of C-type crystals of Neotame has been discovered, and the C-type crystals have been characterized by the XRPD pattern and by solubility.

34. I declare further that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this

application or any patent issuing thereon.

35. Further Declarant saith not.

Jerry Atwood

Jerry Atwood, Ph.D.

March 23, 2004

Date

CURRICULUM VITAE

Jerry L. Atwood

Personal

Date of Birth: July 27, 1942
Place of Birth: Springfield, Missouri
Married: Tracey Machen, 1984

Education

B.S., Southwest Missouri State, Chemistry and Mathematics, 1964
Ph.D., University of Illinois, 1968

Professional Experience

Assistant Professor, University of Alabama, 1968-1972
Associate Professor, University of Alabama, 1972-1978
Professor, University of Alabama, 1978-1987
Visiting Professor, Imperial College, 1977
Visiting Professor, University of Sussex, 1985
University Research Professor, University of Alabama, 1987 - 1994
Senior von Humboldt Fellow, Technical University Berlin, 1989
Professor and Chairman, University of Missouri-Columbia, 1994-
Curators' Professor, University of Missouri-Columbia, 1999-

Professional Activities

Editor, *Journal of Supramolecular Chemistry* (2000-)
Editor, *Supramolecular Chemistry* (1992-2000)
Associate Editor, *Chemical Communications* (1996-)
Consulting Editor, *Journal of Chemical Crystallography* (1999-)
Editor, *Journal of Chemical Crystallography* (1985-1998)
Regional Editor, *Journal of Coordination Chemistry*, A & B (1985-1993)
Editor, *Journal of Inclusion Phenomena* (1983-1991)
Editorial Advisory Board, *Crystal Growth & Design* (2000-)
International Advisory Editorial Board, *New Journal of Chemistry* (2003-)
Editorial Board, *Supramolecular Chemistry* (2000-)
Editorial Board, *Journal of Coordination Chemistry* (1993-)
Editorial Board, *Journal of Organometallic Chemistry* (1986-2000)
Editorial Board, *Crystal Engineering* (1998-)
Co-Editor, *Inclusion Compounds* (five volumes)
Co-Editor, *Comprehensive Supramolecular Chemistry* (ten volumes)
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Member, American Chemical Society

Member, American Institute of Chemical Engineers
Member, American Crystallographic Association
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Publications Summary

Publications in Refereed Journals	588
Patents	10

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Jerry L. Atwood

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Appendix B

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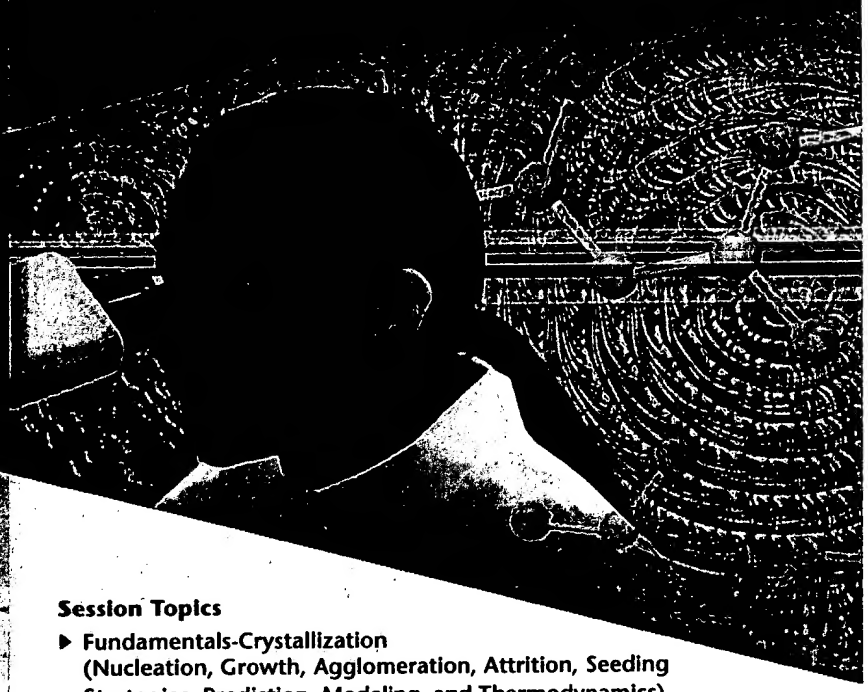

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